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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09-417,522	10/13/1999	MICHAEL NEHLS	8535-027-999	7547

7500

04/23/2002

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EXAMINER

MORAN, MARJORIE A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 04/23/2002

169

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/417,522

Applicant(s)

NEHLS ET AL.

Examiner

Marjorie Moran

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 and 5-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 5-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

All rejections and objections not repeated below are hereby withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

35 U.S.C. 101/112 Utility Rejections

Claims 3 and 5-13 are again rejected, as previously set forth in the office action of 7/17/01, under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

Applicant's arguments filed 1/17/02 have been fully considered but they are not persuasive.

Applicant argues on page 4 of the specification that that the putatively disrupted genes fall within a specific class which are distinct from the general broad class of genes in the genome; however, applicant does not specifically identify the "specific class" of genes to which the claimed polypeptides belong. Applicant argues on page 4 of the response that the genetic loci disrupted by gene trapped sequences (i.e. those corresponding to the claimed sequences) encode genetic functions which are not involved in general survival; i.e. house-keeping functions as both copies of the putatively disrupted allele are not needed for survival. In response, it is noted that merely because a disruption in a genetic allele is not lethal is not necessarily evidence that a gene is NOT involved in "general survival" or is NOT a housekeeping gene. It is noted that many genes do not require that both alleles be functional; e.g. only one allele of most genes

on sex chromosomes are expressed (i.e. functional), generally only one allele for eye color is expressed/functional in humans, etc.

Applicant also argues that, as teratocarcinoma cells are "stem cells" equivalent to embryonic cells, nucleic acid sequences from genes in these cells identified by the gene trapped method of applicants can be used to study development and cell differentiation. However, the specification does not disclose evidence, nor has the applicant presented evidence elsewhere to support this argument. Teratocarcinoma cells presumably do contain genes involved in development and differentiation; however, such cells necessarily also contain genes involved in functions other than development and differentiation, and as set forth above, there is no evidence that the claimed sequences are those involved in development or differentiation. The specification discloses on page 60 that the inventive sequences CAN BE used in cell-based systems to identify compounds which MAY BE involved in development and cell differentiation disorders, but does not specifically identify sequences which are associated with said disorders, nor does the specification disclose that any sequences have been identified which HAVE BEEN used in such a cell-based assay. It is noted that the specification also discloses on page 55 that the inventive sequences can also be used to identify signal transduction pathways and catalytic events, but does not specifically identify which sequences are associated with such pathways or events.

Applicant is reminded that a "use" to do further research (e.g. to identify a gene which is involved in development, differentiation, signal transduction, etc.) is not considered a specific, substantial, and credible utility. As set forth above, a

method of making a compound without utility does not itself have utility. The same is true for a method of use of a compound without utility.

For the reasons set forth above, applicant's arguments are not convincing, and the rejection is maintained.

Claims 3 and 5-13 are again rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth and maintained above, one skilled in the art would not know how to use the claimed invention.

Claim Rejections - 35 USC ' 112

Claims 3 and 10-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a WRITTEN DESCRIPTION rejection.

Applicant's arguments filed 1/17/02 have been fully considered but they are not persuasive. Applicant again argues that the claimed sequences are identified by structure/formula (i.e. sequence) and/or by functional property (i.e. ability to hybridize to certain sequences). Applicant further argues that the specification discloses exemplary elements which may be included in the claimed polynucleotides, and that one skilled in the art can readily isolate and distinguish polypeptides with the claimed hybridization properties recited in claim 13. In response, it is noted that a large variety of noncoding regions, regulatory sequences, and vector sequences are known in the art, and are not described in the instant specification. In addition, since the claims recite open language, the

claimed polynucleotides may comprise repetitive sequences, and, potentially, entire genes or coding regions not disclosed by the instant specification. It is also noted that the fact that one skilled in the art can identify and distinguish polypeptides based on hybridization properties does not constitute a written description of the polypeptide, sequence, structure, etc. so identified.

For these reasons and those previously set forth, the examiner maintains that none of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claims, therefore the rejection is maintained.

Conclusion

Claims 3 and 5-13 are again rejected.


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

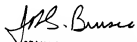
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a patent analyst, Tina Plunkett, whose telephone number is (703) 305-3524.


Marjorie A. Moran
Examiner
Art Unit 1631

April 19, 2002


JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER